衞生署藥物辦公室
藥物註冊及進出口管制部

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DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION
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382 Nam Cheong Street, Kowloon, Hong Kong

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(來函請敍明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

Recommendation to restrict the use of domperidone in the European Union

Your attention is drawn to the announcement from the European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) on the recommendation to restrict the use of domperidone. Serious effects on the heart, including QT prolongation and arrhythmias, were previously evaluated by EMA; and in 2011, the product information for domperidone-containing medicines in the European Union (EU) were updated to reflect the risk of these adverse events and to warn that domperidone should be used with caution in patients with certain heart conditions. However, cases of heart problems in patients using the medicine continued to be reported. Therefore, the PRAC conducted another review to examine the risk-benefit ratio of domperidone. The PRAC has completed the review recently, and recommended changes to their use throughout the EU, including using these medicines only to relieve symptoms of nausea and vomiting, restricting the dose and adjusting doses carefully by weight where it is licensed in children. Reducing the recommended dose and duration of treatment was considered key to minimising its risks.

The PRAC recommended that domperidone-containing medicines should remain available and may continue to be used in the EU for the management of the symptoms of nausea and vomiting, but that the recommended dose should be reduced to 10 mg up to three times daily by mouth for adults and adolescents weighing 35 kg or more. These patients may also be given the medicine as suppositories of 30 mg twice daily. Where the medicine is licensed in children and adolescents weighing less than 35 kg, it should be given by mouth at a dose of 0.25 mg per kg bodyweight up to three times daily. The medicine should not normally be used for longer than one week.

In addition, domperidone should no longer be authorised to treat other conditions such as bloating or heartburn. It must not be given to patients with moderate or severe impairment of liver function, or in those who have existing abnormalities of electrical activity in the heart or heart rhythm, or who are at increased risk of such effects. Besides, it must not be used with other medicines that have similar effects on the heart or reduce the breakdown of domperidone in the body. Products supplying a dose of 20 mg by mouth, and suppositories of 10mg or 60 mg are no longer recommended for use and should be withdrawn.

Please refer to the following website of EMA for details of the announcement:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/03/news_detail_002039.jsp&mid=WC0b01ac058004d5c1

In Hong Kong, there are 51 registered pharmaceutical products containing domperidone. On 8 March 2012, the Department of Health had sent letters to inform healthcare professionals on the issue of domperidone associated with increased risk of serious abnormal heart rhythms and sudden cardiac death. Subsequently, the Registration Committee of the Pharmacy and Poisons Board (the Registration Committee) decided that the sales pack or package insert of domperidone-containing products had to be updated to include the appropriate safety information. In view of the EMA's latest recommendation, the matter will be discussed in the meeting of the Registration Committee. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2186 9845 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Mr. Grant NG)
for Assistant Director (Drug)